



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

**Public Health Service  
Food and Drug Administration**

m40521  
San Francisco District  
1431 Harbor Bay Parkway  
Alameda, CA 94502-7070  
Telephone: 510/337-6700

**VIA FEDERAL EXPRESS**

Our Reference: 2935829

August 9, 2000

Edwin R. Wong, President  
Sun Sen Salad Co., Inc.  
290 Commerce Circle  
Sacramento, CA 95815

**WARNING LETTER**

Dear Mr. Wong:

The U.S. Food and Drug Administration (FDA) conducted an inspection of your facility located at 290 Commerce Circle, Sacramento, CA on July 17, 2000.

The inspection revealed lack of implementation of the recommended practice of microbial testing of spent irrigation water from your sprout processing. This causes your firm's sprouts to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) because they are produced under insanitary conditions that may render them injurious to health. The conditions under which the sprouts are produced are considered insanitary since effective preventive controls, particularly microbial testing of spent irrigation water, have not been adopted and implemented by your firm.

Furthermore, the inspection revealed insanitary practices and conditions which cause all foods to be adulterated within the meaning of Section 402(a)(4) of the Act because they have been prepared, packed or held under insanitary conditions whereby they may have been contaminated with filth.

The following is a list of the insanitary practices, conditions, and findings observed by Investigator Joan T. Briones:

**BEAN SPROUT PROCESSING**

1. **FAILURE TO PERFORM MICROBIAL TESTING OF SPENT IRRIGATION WATER:** A copy of the guidance document, "Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production," is enclosed. This guidance document is intended to assist sprout manufacturers in implementing one of the principal recommendations in the guidance document, "Reducing Microbial Food Safety Hazards For Sprouted Seeds," which is also enclosed.

FDA currently recommends the treatment of pre-washed seed with 2% (20,000 ppm available chlorine) calcium hypochlorite solution for 15 minutes at room temperature with continuous agitation. The ratio of five (5) pounds of seed in one gallon 2% calcium hypochlorite solution is recommended. See enclosed EPA Reg. #1258-427.

2. **DAMAGED SCREENS ON THREE GERMINATING DRUMS ARE REPAIRED WITH DUCT TAPE:** The duct tape, which comes into direct contact with sprouts, cannot be adequately cleaned and sanitized.
3. **DUCT TAPE COVERS THE EDGES OF THE STAINLESS STEEL TABLE IN THE PACKING AREA:** The duct tape, which comes into direct contact with produce, cannot be adequately cleaned and sanitized.
4. **CROSS-CONTAMINATION WAS NOTED FROM THE FLOOR TO CUT VEGETABLES:** An employee was noted emptying the food contents of a grey perforated plastic container with a gloved hand on the container bottom which had previously been in contact with the processing room floor. The employee subsequently handled cut vegetables without changing the glove or sanitizing the glove.
5. **WATER SUPPLY HOSES TO THE SPROUT GERMINATION DRUMS LACK BACKFLOW PREVENTION DEVICES. WATER SUPPLY HOSE USED TO CLEAN EQUIPMENT AND UTENSILS, NOTED TO BE IN DIRECT CONTACT WITH THE FLOOR, ALSO LACKS A BACKFLOW PREVENTION DEVICE:** These conditions can lead to the back flow of water from the sprout germination drums or from the processing room floor into the potable water supply.
6. **UNCOVERED DRAIN NEAR THE CENTER OF THE SPROUT ROOM:** This condition could allow the entrance of pests into the facility.
7. **BAG OF ONIONS WAS OBSERVED TO BE ON THE FLOOR:** This condition could allow cross contamination of product with filth or microbiological contaminants from the processing room floor.

At the conclusion of the inspection, the insanitary practices and conditions and the lack of implementation of currently recommended practices were listed on Form FDA 483 (Inspectional Observations) and discussed with you. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations.

You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice. These include seizure and/or injunction. FDA will consider enforcement actions against any party who does not have effective preventive controls in place with respect to sprouts, in particular, effective microbial testing.

Please advise FDA in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 days, state the reasons for the delay and the time at which the corrections will be completed.

Your response should be directed to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070.

Sincerely,



Mary H. Woleske  
Acting District Director  
San Francisco District

Enclosures:

Guidance for Industry Document, "Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production"

Guidance for Industry Document, "Reducing Microbial Food Safety Hazards For Sprouted Seeds"

EPA REG. #1258-427

Form FDA 483